

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiesa: COMMISSIONER FOR PATENTS P O Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/566,593 | 08/17/2006 | Motoyuki Ashikari | SHZ-028US | 3574 |
| 959 087212909 LAHIVE & COCKFIELD, LLP FLOOR 30, SUITE 3000 | | | EXAMINER | |
| | | | BUI, PHUONG T | |
| ONE POST OFFICE SQUARE BOSTON, MA 02109 | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/21/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/566,593 ASHIKARI ET AL. Office Action Summary Examiner Art Unit Phuona T. Bui 1638 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on 29 January 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.3-14 and 16-22 is/are pending in the application. 4a) Of the above claim(s) 12-14.16 and 18-22 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1,3-11 and 17 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

2) 1 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 8/16/06,12/11/06.

Paper No(s)/Mail Date ____

6) Other:

Notice of Informal Patent Application (PTO-152)

Application/Control Number: 10/566,593 Page 2

Art Unit: 1638

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed January 29, 2009. Applicant elects Invention I with traverse. Applicant traverses primarily that Inventions I and II should be rejoined in light of Applicant's amendment. Applicant's traversal is persuasive. Claims 1, 3-14 and 16-22 are pending. Claims 1, 3-11 and 17 are examined in the instant application. Claims 12-14, 16 and 18-22 are withdrawn from examination. This restriction is made FINAL.

Applicant shall have benefit of priority filing date of July 30, 2004.

Information Disclosure Statement

 Applicant's IDS filed August 16, 2006 and December 11, 2006 are attached to the instant Office action. The references have been considered to the extent of the English translation available.

Drawings

3. The drawings submitted January 31, 2006 are acceptable for examination only but are not acceptable for publication. New corrected drawings in compliance with 37 CFR 1.121(d) are required. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Application/Control Number: 10/566,593

Art Unit: 1638

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1(b) and 3, it is suggested "a coding region" be amended to "the coding region" because "a coding region" reads on a codon, which does not appear to be Applicant's intention.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing the regeneration ability of a plant when compared to an untransformed plant, does not reasonably provide enablement for altering the regeneration ability of a plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The breadth of "altering" encompasses increasing and decreasing the regeneration ability of a plant. Applicant's working examples show that expressing the DNA encoding SEQ ID NO:3 increases the regeneration ability of a plant. Applicant does not having working examples for decreasing the regeneration ability of a plant.

Application/Control Number: 10/566,593

Art Unit: 1638

Applicant provided no guidance as to how SEQ ID NO:1, 2 or 3 can be used to decrease the regeneration ability of a plant. While technologies exist to decrease a protein function such as via antisense or cosuppression, it is unpredictable that these would be applicable to the claimed sequences because all plants possess the ability to regenerate (p1, ln. 26), and it is unclear how an antisense or sense strand would affect such a complex plant phenomenon such as plant regeneration, if at all.

Thus, Applicant has not enabled the claimed invention as commensurate in scope with the claims without undue experimentation.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1, 4, 6-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terada et al. (Biosci. Biotechnol. Biochem., Vol. 59, pp. 2183-2185, 1995 (Applicant's IDS)).

Terrada teaches a rice ferredoxin nitrite reductase which has 99.8% sequence identity to SEQ ID NO:3, as well as vector and host cell. The sequence of Terrada has 2 conservative amino acid differences when compared to SEQ ID NO:3. Terrada also teaches ferredoxin nitrite reductase is required for assimilation of nitrate in plants by reducing nitrite to ammonia (p. 2183).

Terrada does not teach SEQ ID NO:3 or a plant transformant.

Application/Control Number: 10/566,593

Art Unit: 1638

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to express SEQ ID NO:3 containing conservative amino acid substitutions in a plant transformant for the purpose of expressing ferredoxin nitrite reductase in a plant host with a reasonable expectation of success. Ferredoxin nitrite reductase is an important plant enzyme. The use of conservative amino acid substitutions and plant optimized codon are well known in the art. The use of a plant host to produce a protein of interest is also not novel. Claim 17 is a product claim and thus its intended use holds little patentable weight. Moreover, the expression of the protein of Terrada would result in increased regeneration ability in the transformed plant host. Thus, one skilled in the art would have been motivated to express SEQ ID NO:3 with its conservative amino acid substitutions in a plant host to obtain ferredoxin nitrite reductase without any surprising or unexpected results.

Remarks

- 10. No claim is allowed.
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/566,593 Page 6

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/ Primary Examiner, Art Unit 1638

5/20/09